



10/083,960

FORM PTO-1449 (Modified)	Attorney Docket No.: 019801-000230US	Application No.: 09792,400
LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)	Applicant: Rothbard, et al.	
	Filing Date: February 23, 2001	Group: 1615

Reference Designation U.S. PATENT DOCUMENTS Page 1

Examiner Initial	Document No.	Date	Name	Class	Sub-class	Filing Date (If Appropriate)
<u>RL</u> 1	4,880,911	11/14/89	Brewer, et al.	530	351	
<u>RL</u> 2	4,847,240	7/11/89	Ryser, et al.	514	12	
<u>RL</u> 3	4,701,521	10/20/87	Ryser, et al.	530	322	
<u>RL</u> 4	4,631,190	12/23/86	Shen, et al.	424	85	
<u>RL</u> 5	4,532,207	7/30/85	Brewer, et al.	435	68	
<u>RL</u> 6	5,783,178	7/21/98	Kabanov, et al.	424	784	
<u>RL</u> 7	5,795,909	8/18/98	Shashoua	514	449	
<u>RL</u> 8	5,831,001	11/03/98	Twist, et al.	530	328	
<u>RL</u> 9	5,789,531	8/04/98	Sumner-Smith, et al.	530	328	
<u>RL</u> 10	5,716,614	2/10/98	Katz, et al.	424	743	
<u>RL</u> 11	5,674,849	10/07/97	Twist, et al.	514	15	
<u>RL</u> 12	5,646,120	07/08/97	Sumner-Smith, et al.	514	14	
<u>RL</u> 13	5,633,230	05/27/97	Twist, et al.	514	15	
<u>RL</u> 14	5,354,844	10/11/94	Beug, et al.	530	345	
<u>RL</u> 15	5,162,505	11/10/92	Dean, et al.	530	391.5	
<u>RL</u> 16	5,804,604	09/08/98	Frankel, et al.	530	324	
<u>RL</u> 17	5,362,831	11/08/94	Mongelli, et al.	526	304	
<u>RL</u> 18	5,028,707	07/02/91	Nichols, et al.	546	156	
<u>RL</u> 19	4,046,722	09/06/77	Rowland	530	362	
<u>RL</u> 20	5,977,163	11/02/99	Li, et al.	514	449	
<u>RL</u> 21	6,077,835	06/20/00	Hanson, et al.	514	44	

## FOREIGN PATENT DOCUMENTS

	Document No.	Date	Country	Class	Sub-class	Translation (Yes/No)
<u>RL</u> 22	2,094,658	10/24/93	Canada			
<u>RL</u> 23	EP 0009498	06/27/84 04/80	Europe			
<u>RL</u> 24	WO 91/09958	07/11/91	PCT			
<u>RL</u> 25	WO 98/52614	11/26/98	PCT			
<u>RL</u> 26	EP 0 599 303	06/01/94	Europe			
<u>RL</u> 27	WO 97/40854	11/06/97	PCT			
<u>RL</u> 28	WO 97/33552	09/18/97	PCT			
<u>RL</u> 29	WO 96/21036	07/11/96	PCT			
<u>RL</u> 30	WO 95/11038	04/27/95	PCT			
<u>RL</u> 31	WO 94/14464	07/07/94	PCT			
<u>RL</u> 32	WO 94/04686	03/03/94	PCT			
<u>RL</u> 33	WO 93/21941	11/11/93	PCT			

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Attorney Docket No.: 019801-000230US Application No. ~~097792,480~~

Applicant: Rothbard, et al.

Filing Date: February 23, 2001 Class Subclass

Group: 1615

34	WO 93/04701	03/18/93	PCT			
35	WO 92/07871	05/14/92	PCT			
36	WO 91/09958	07/11/91	PCT			
37	WO 79/00515	08/09/79	PCT			
38	WO 01/13957	03/01/01	PCT			
39	GB 744 988	02/15/56	Germany			
40	JP 10 095738	04/14/98	Japan			

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**OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)**

41	Arbuck, et al. "Taxol: Clinical Results and Current Issues in Development"; Chapter 14 in <i>TAXOL®: Science and Applications</i> , M. Suffness ed., CRC Press (New York), p. 379-415 (1995)
42	Balicki, et al. "Histone H2A Significantly Enhances In Vitro DNA Transfection"; <i>Molecular Medicine</i> Vol. 3, No. 11 p. 782-787 (1997)
43	Boussif, et al. "A versatile vector for gene and oligonucleotide transfer into cells in culture and in vivo: Polyethylenimine"; <i>Proc. Natl. Acad. Sci. USA</i> Vol. 92, p. 7297-7301 (August 1995)
44	Burton, et al. "Basic polyelectrolytes and protein transport across the new-born pig intestine"; <i>Physiological Society</i> p. 27P-28P (Sep. 1970), Vol. 211, No. 2
45	Brugidou, et al. "The Retro-Inverso Form of a Homeobox-Derived Short Peptide is Rapidly Internalised by Cultured Neurones: A New Basis For An Efficient Intracellular Delivery System"; <i>Biochemical and Biophysical Research Communications</i> Vol. 214, No. 2 p. 685-693 (Sep. 1995)
46	Buschle, et al. "Transloading of tumor antigen-derived peptides into antigen-presenting cells"; <i>PNAS</i> Vol. 94, p. 3256-3261 (April 1997)
47	Chen, et al. "Galactosylated Histone-Mediated Gene Transfer and Expression"; <i>Human Gene Therapy</i> Vol. 5, p. 429-435 (1994)
48	Cooke, et al. "NITRIC OXIDE SYNTHASE: Role in the Genesis of Vascular Disease"; <i>Annu. Rev. Med.</i> Vol. 48, p. 489-509 (1997)
49	Dattilo, et al. "Inducible Nitric Oxide Synthase Expression in Human Vein Grafts"; <i>Am J Surg.</i> Vol. 174, p. 177-180 (1997)
50	de Bont, et al. "Synthesis and Biological Activity of $\beta$ -Glucuronyl Carbamate-Based Prodrugs of Paclitaxel as Potential Candidates for ADEPT"; <i>Bioorganic &amp; Medicinal Chemistry</i> Vol. 5, No. 2 p. 405-414 (1997)
51	Derossi, et al. "The Third Helix of the Antennapedia Homeodomain Translocates through Biological Membranes"; <i>The Journal of Biological Chemistry</i> Vol. 269, No. 14 p. 10444-10450 (1994)
52	Elferink, "Changes of Plasma Membrane Permeability in Neutrophils Treated With Polycations"; <i>Inflammation</i> Vol. 15, No. 2 p. 103-115 (Apr. 1991)
53	Emi, et al. "Gene Transfer Mediated by Polyarginine Requires a Formation of Big Carrier-Complex of DNA Aggregate"; <i>Biochemical and Biophysical Research Communications</i> Vol. 231, p. 421-424 (1997)
54	Fawell, et al. "Tat-mediated delivery of heterologous proteins into cells"; <i>Proc. Natl. Acad. Sci. USA</i> Vol. 91, p. 664-668 (Jan. 1994)
55	Fletcher, et al. "Partially Modified Retro-Inverso Peptides: Development, Synthesis, and Conformational Behavior"; <i>Chem. Rev.</i> Vol. 96 p. 763-795 (1998)
56	Garg, et al. "Nitric Oxide-generating Vasodilators and 8-Bromo-Cyclic Guanosine Monophosphate Inhibit Mitogenesis and Proliferation of Cultured Rat Vascular Smooth Muscle Cells"; <i>J. Clin. Invest.</i> Vol. 83, p. 1774-1777 (May 1989)
57	Georg, et al. "The Medicinal Chemistry of Taxol"; Chapter 13 in <i>TAXOL®: Science and Applications</i> , M. Suffness ed., CRC Press (New York), p. 317-375 (1995)

Jeffrey E. Russel

March 9, 2006



10/083,960

FORM PTO-1449 (Modified)		Attorney Docket No.: 019801-000230US	Application No. <del>019801-000230US</del>
LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)		Applicant: Rothbard, et al.	
		Filing Date: February 23, 2001	Group: 1615
<u>58</u>	Golik, et al. "Synthesis and Antitumor Evaluation of Paclitaxel Phosphonooxymethyl Ethers: A Novel Class of Water Soluble Paclitaxel Pro-Drugs" <i>Bioorganic &amp; Medicinal Chemistry Letters</i> Vol. 6, No. 15 p. 1837-1842 (1996)		
<u>59</u>	Greenwald, et al. "Drug Delivery Systems: Water Soluble Taxol 2'-Poly(ethylene glycol) Ester Prodrugs-Design and in Vivo Effectiveness"; <i>J. Med. Chem.</i> 39(2):424-431 (Jan. 1996)		
<u>60</u>	Kessler "Peptoids-A New Approach to the Development of Pharmaceuticals"; <i>Angew Chem. Int. Ed. Engl.</i> Vol. 32, No. 4 p. 543-544 (1993)		
<u>61</u>	Kingston "Natural Toxoids: Structure and Chemistry"; Chapter 12 in <i>TAXOL®: Science &amp; Applications</i> , M. Suffness ed, CRC Press (New York), p. 287-315 (1995)		
<u>62</u>	Lam, et al. "The "One-Bead-One-Compound" Combinatorial Library Method"; <i>Chem. Rev.</i> Vol. 97, p. 411-448 (1997)		
<u>63</u>	Lloyd-Jones, M.D., et al. "The Vascular Biology of Nitric Oxide and Its Role in Atherogenesis"; <i>Annu. Rev. Med.</i> Vol. 47, p. 365-375 (1996)		
<u>64</u>	Mauersberger, et al. "Untersuchungen zur Zytotoxizität von Poly-L-Arginin, Poly-L-Lysin and DEAE-Dextran bei L-Zellen und Mäuseembryofibroblasten"; <i>Exp. Path.</i> Vol. 18 p. 268-274 (1977)		
<u>65</u>	Murphy, et al. "A combinatorial approach to the discovery of efficient cationic peptoid reagents for gene delivery"; <i>Proc. Natl. Acad. Sci. USA</i> Vol. 95, p. 1517-1522 (Feb. 1998)		
<u>66</u>	Natsume, et al. "Screening of Absorption Enhancers for Nasal Peptide and Protein Delivery"; <i>Proceed. Intern. Symp. Control. Rel. Bioact. Mater.</i> Vol. 23, P. 481-482 (July 1996)		
<u>67</u>	Nicolaou, et al. "Design, synthesis and biological activity of protaxols"; <i>Nature</i> Vol. 364, p. 464-466 (July 1993)		
<u>68</u>	Rodrigues, et al. "Synthesis and $\beta$ -lactamase-mediated activation of a cephalosporin-taxol prodrug" <i>Chemistry and Biology</i> Vol. 2, p. 223-227 (Apr. 1995)		
<u>69</u>	Rose, "Preclinical Antitumor Activity of Taxanes"; Chapter 8 in <i>TAXOL®: Science &amp; Applications</i> , M. Suffness ed., CRC Press (New York), p. 209-235 (1995)		
<u>70</u>	Simon, et al. "Peptoids: A modular approach to drug discovery"; <i>Proc. Natl. Acad. Sci. USA</i> Vol. 89 p. 9367-9371 (Oct. 1992)		
<u>71</u>	Straubinger "Biopharmaceutics of Paclitaxel (Taxol): Formulation, Activity, and Pharmacokinetics"; Chapter 9 in <i>TAXOL® Science and Applications</i> , M. Suffness ed., CRC Press (New York), p. 237-258 (1995)		
<u>72</u>	Sumner-Smith, et al. "123: 79357m Antiherpetic activities of N- $\alpha$ -acetyl-nona-D- $\epsilon$ -arginine amide acetate"; <i>6001 Chemical Abstracts</i> Vol. 123, No. 7 p. 606 (1995)		
<u>73</u>	Thompson, et al. "Synthesis and Applications of Small Molecule Libraries"; <i>Chem. Rev.</i> 96:555-600 (1996)		
<u>74</u>	Tsao, et al. "Nitric Oxide Regulates Monocyte Chemotactic Protein-1"; <i>Circulation</i> 96:, 934-940 (1997)		
<u>75</u>	Uchida, et al. "Polycations Decrease the Transepithelial Resistance of Cultured Tracheal Epithelial Cells"; <i>Chest</i> Vol. 101, No. 3, p. 33S (March 1992)		
<u>76</u>	Ueda, et al. "Synthesis and Antitumor Evaluation of 2'-Oxycarbonylpaclitaxels (Paclitaxel-2'-Carbonates)"; <i>Bioorganic &amp; Medicinal Chemistry Letters</i> Vol. 4 No. 15 p. 1861-1864 (Aug. 1994)		
<u>77</u>	Ueda, et al. "Novel Water Soluble Phosphate Prodrugs of Taxol® Possessing In Vivo Antitumor Activity"; <i>Bioorganic &amp; Medicinal Chemistry Letters</i> Vol. 3, No. 8:1761-1766 (May 1993)		
<u>78</u>	Vyas, et al. "Synthesis and Antitumor Evaluation of Water Soluble Taxol Phosphates"; <i>Bioorganic &amp; Medicinal Chemistry Letters</i> Vol. 3, No. 6 p. 1357-1360 (1993)		
<u>79</u>	Vyas, et al. "Phosphatase-Activated Prodrugs of Paclitaxel"; Chapter 9 in <i>Taxane Anticancer Agents</i> American Chemical Society p. 124 (1995)		
<u>80</u>	Wolf, et al. "Dietary L-Arginine Supplementation Normalizes Platelet Aggregation in Hypercholesterolemic Humans"; <i>JACC</i> Vol. 29, No. 3 p. 479-485 (March 1997)		
<u>81</u>	Zuckermann, et al. "Efficient Method for the Preparation of Peptoids [Oligo(N-substituted glycines)] by Submonomer Solid-Phase Synthesis"; <i>Chemtracts-Macromolecular Chemistry</i> Vol. 4 p. 80-83 (1993)		
<u>82</u>	Aoyagi, et al. "Polymerization of Benzalkonium Chloride-Type Monomer and Application to Percutaneous Drug Absorption Enhancer"; <i>Journal of Controlled Release</i> , Vol 13, No. 1 pp. 63-71 (July 1990)		

Jeffrey E. Russell

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10/083,960

FORM PTO-1449 (Modified)		Attorney Docket No.: 019801-000210US	Application No.: <del>60241-88</del>
LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)		Applicant: Rothbard, et al.	
		Filing Date: August 24, 2000	Group: 1642
JR 83	Babiuk, et al., "Cutaneous vaccination: the skin as an immunologically active tissue and the challenge of antigen delivery"; <i>Journal of Controlled Release</i> Vol. 66 pp. 199-214 (2000)		
JR 84	Colin, et al. "Liposomes enhance delivery and expression of an RGD-oligolysine gene transfer vector in human tracheal cells"; <i>Gene Therapy</i> Vol. 5 pp. 1488-1498 (1998)		
JR 85	Coyle, et al. "Role of Cationic Proteins in the Airway Hyperresponsiveness Due to Airway Inflammation"; <i>Am. Respir. Crit. Care Med.</i> Vol. 150 pp. 563-571 (1994)		
JR 86	Gama, et al. "Ca <sup>2+</sup> -sensing receptors in intestinal epithelium"; <i>American Journal of Physiology</i> Vol. 273, No. 4, Part 1 pp. C1168-C1175 (Oct. 1997)		
JR 87	Hosoya, et al. "Effect of Several Hydrophilic Polymers on the Permeation of Morphine and Salicylic Acid through Excised Hairless Rat Skin"; <i>Chem. Pharm. Bull.</i> 46(5) 882-885 (1998)		
JR 88	Hulsmann, "Permeability of Human Isolated Airways Increases after Hydrogen Peroxide and Poly-L-arginine"; <i>Am. J. Respir. Crit. Care Med.</i> Vol 153 pp. 841-846 (1996)		
JR 89	Koji Kobayashi, "Composition for Transmucosally Absorbable Preparation"; Patent Abstracts of Japan, Publication No. 10095738, Publication Date April 4, 1998		
JR 90	Perr, et al. "Protamine Selectively Inhibits Collagen Synthesis by Human Intestinal Smooth Muscle Cells and Other Mesenchymal Cells"; <i>Journal of Cellular Physiology</i> 140:463-470 (1989)		
JR 91	Peterson, et al. "Polyamino Acid Enhancement of Bacterial Phagocytosis by Human Polymorphonuclear Leukocytes and Peritoneal Macrophages"; <i>Infection and Immunity</i> Vol. 43, No. 2, pp. 561-566 (Feb. 1984)		
JR 92	Santana, et al., "Inflammatory responses induced by poly-L-arginine in rat lungs <i>in vivo</i> "; <i>Agents Actions</i> Vol. 39, No. 3-4 pp. 104-110 (1993)		
JR 93	Tzan, et al. "Mammalian urinary bladder permeability is altered by cationic proteins modulation by divalent cations"; <i>American Journal of Physiology</i> Vol. 267, No. 4, Part 1, pp. C1013-C1026 (1994)		
JR 94	Tzan, et al., "Modification of Epithelial Permeability by Cationic Polypeptides"; <i>American Journal of Physiology</i> Vol. 265, No. 6, Part 1, pp. C1637-C1647 (1993)		
JR 95	Uchida, et al., "Cationic Proteins Increase the Permeability of Cultured Rabbit Tracheal Epithelial Cells: Modification by Heparin and Extracellular Calcium"; <i>Experimental Lung Research</i> Vol. 22, No. 1, pp. 85-99 (1996)		
JR 96	Wei, et al. "synthesis of Oligoarginine-Oligonucleotide Conjugates and Oligoarginine-Bridge Oligonucleotide Pairs"; <i>Bioconjugate Chem.</i> Vol. 5, pp. 468-474 (Sept./Oct. 1994)		
JR 97			
EXAMINER Jeffrey C. Auel		DATE CONSIDERED	<del>August 11, 2000</del> March 9, 2006



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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)			<b>Complete if Known</b>		
			Application Number	10/083,960	
			Filing Date	February 25, 2002	
			First Named Inventor	Rothbard, Jonathan B., et. al.	
			Art Unit	1653	
			Examiner Name		
Sheet	1	of		Attorney Docket Number	019801-000240US

U.S. PATENT DOCUMENTS					
Examiner	Cite No. <sup>1</sup>	Document Number Number Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
JRK	1	US-6,089,234	07/18/00	Bretton	128/898

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Country Code <sup>3</sup>	Number <sup>4</sup> Kind Code <sup>5</sup> (if known)			

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